

**UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION**

JERAD SHORT,  
A Michigan Individual,  
Plaintiff,

Case No.: 14-cv-1025

v.

Hon.:

JANSSEN PHARMACEUTICALS, INC.  
A New Jersey Corporation,  
JOHNSON AND JOHNSON, INC.,  
A New Jersey Corporation,  
Defendant.

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There is no other pending or resolved civil action arising out of the same transaction or  
occurrence as alleged in the Complaint

**VERIFIED COMPLAINT and JURY DEMAND**

**PLAINTIFF DEMANDS A JURY TRIAL**

## **STATEMENT OF THE CASE**

This claim stems from the Defendants' unlawful marketing of the drug Risperdal. As of March 2002, the FDA had approved Risperdal for the treatment of schizophrenia only and was not approved for any use in children and adolescents. Despite this fact, and prior to this date, Defendants engaged in active solicitation of doctors, hospitals, and healthcare professionals to proscribe the drug to adolescents. Further, Defendants knew that the drug had grave risks of causing physical malformations in young males but knowingly downplayed these risks in its marketing endeavors. Defendants put their desire for profits ahead of the public health. In 2013, Defendants pled guilty to criminal charges and agreed to pay \$2.2 billion to resolve criminal and civil liability related, in part, to the misbranding and wrongful promotion of Risperdal. Jerad Short, the Plaintiff, was one of the many, many victims of Defendants' misbranding and false representations pertaining to Risperdal. His doctors prescribed the drug to him between approximately 1994 and 1999 as a result of Defendants' efforts. As a result, he now suffers from gynecomastia, a known side effect of adolescent exposure to Risperdal. He now seeks recovery for his substantial losses that were a direct result of Defendants' unlawful conduct.

## **JURISDICTION and VENUE**

1. Plaintiff JERAD SHORT is a permanent resident and domiciliary of the State of Michigan. He owns no real property and has no permanent or temporary residence in the State of New Jersey. He is, therefore, a citizen of the State of Michigan and *not* a citizen of the State of New Jersey, as defined by 28 USC § 1332(a)(1).

2. This claim stems from the actions and omissions of the corporate entity formerly known as “Janssen Pharmaceutica, Inc” during the period of time between 1993 and present. Upon information and belief, the corporate entity “Janssen Pharmaceutica, Inc” was involved in a corporate reorganization in December 2007 wherein the entity was combined with other Johnson & Johnson subsidiaries to form a new wholly-owned subsidiary named “Ortho-Mcneil-Janssen Pharmaceuticals, Inc” which, in 2011, was renamed to Janssen Pharmaceuticals, Inc. Wherefore, Defendant Janssen Pharmaceuticals, Inc. became a successor in liability to the actions of the former corporate entity “Janssen Pharmaceutica, Inc.”

3. Defendant JANSSEN PHARMACEUTICALS, INC. (“Janssen”) is the successor corporation to a business entity known as “Janssen Pharmaceutica, Inc.” This entity is incorporated and has principle place of operations in New Jersey. This entity, therefore, is a citizen of New Jersey for purposes of 28 USC § 1332 *et seq.* This business entity is, or at times described in this Complaint was, a wholly owned subsidiary of Defendant Johnson and Johnson, Inc.

4. Defendant JOHNSON & JOHNSON, INC (“Johnson”) is a corporation organized under the law of New Jersey, with principle place of operations in that state. This entity, therefore, is a citizen of New Jersey for purposes of 28 USC § 1332 *et seq.* Defendant Johnson approved and ratified Janssen’s conduct as alleged herein.

5. From the time period between 1996 and present, Defendants Janssen and Johnson directly or indirectly designed, tested, manufactured, labeled, advertised, marketed, promoted, distributed, and sold the drug Risperdal, a prescription product, throughout the United States including the Western District of Michigan.

6. Plaintiff Short was prescribed Risperdal in the Western District of Michigan, developed gynecomastia in the Western District of Michigan, and presently works and resides in the Western District of Michigan.

7. The Court may exercise *general in personem* jurisdiction over Defendants Janssen and Johnson because of these entities' systematic and continuous direction of business activities into the Western District of Michigan through the described conduct involving Risperdal. In the alternative, the Court may exercise *specific* jurisdiction over the claims alleged that resulted from a series of transactions and occurrences in the Western District of Michigan, related to Defendants' knowing direction of activities into this district, the damages from which were felt, and would reasonably be expected to be felt, within this district.

8. The Western District of Michigan is the proper venue for the claims, pursuant to 28 USC § 1391(b)(2), because a substantial part of the events or omissions giving rise to the claim occurred herein. In the alternative, venue would be proper pursuant to 28 USC § 1391(b)(3). In addition, venue is proper as to the RICO claims, pursuant to 18 USC § 1965(a), because the Defendants transact their affairs in the Western District of Michigan.

9. The Court may exercise *subject matter jurisdiction* over the claims brought pursuant to the federal RICO Act, 18 USC § 1962(c) and (d), pursuant to 28 USC § 1331. The Court may exercise pendent jurisdiction over the remaining State claims, pursuant to 28 USC § 1367.

10. In addition, the state law claims exceed \$75,000 in value and are between two parties of diverse citizenship. For this reason, the Court may also exercise *subject matter jurisdiction* of the State law claims, pursuant to 28 USC § 1332(a).

### COMMON ALLEGATIONS

11. Plaintiff repeats and re-alleges the factual statements and legal assertions contained in the previous numbered paragraphs as if fully restated herein.

#### *Risperdal Label*

12. On December 29, 1993, the FDA approved Risperdal for “management of the manifestations of psychotic disorders” in adults.

13. On September 17, 1997 Defendant Janssen sought to add pediatric use to the Risperdal label. The FDA denied this request, stating

We must conclude that there is inadequate support for the changes sought. As noted, you have not identified any pediatric indications for which you believe Risperdal could be approved and you have provided no data from adequate and well controlled trials to support any such approvals. There were no specific safety findings of sufficient concern among the meager safety data submitted to justify adding any information to labeling about the safety experience with this drug in the pediatric age group. *To permit the inclusion of the proposed vague references to the safety and effectiveness of Risperdal in pediatric patients and the nonspecific cautionary advice about how to prescribe Risperdal for the unspecified target indications would serve only to promote the use of this drug in pediatric patients without any justification.* Consequently, this supplement is not approved. **Ex. A** (*emphasis added*).

14. On March 3, 2000 Janssen met with the FDA to discuss, among other things, whether a proposed safety study “is ... adequately designed to provide sufficient pK/safety data for inclusion in the labeling for a pediatric population.” The proposed population for the study was groups 5-16 years old. **Ex. B.**

15. On March 3, 2002, the FDA approved revised labeling for Risperdal to state that Risperdal is indicated for “the treatment of schizophrenia.”

16. On December 4, 2003, the FDA approved Risperdal for the short-term treatment of acute manic or mixed episodes associated with Bipolar I disorder in *adults*.

17. Between 1993 and 2005, Risperdal was not approved by the FDA for any other conditions in adults than those listed in the foregoing paragraphs or for use in children for any purpose.

18. In or about 2006 and 2007, the FDA approved Risperdal for the treatment of irritability associated with autistic disorder in children and adolescents, schizophrenia in adolescents, and Bipolar I disorder in children and adolescents.

*Janssen & Johnson's Unlawful Promotion of Risperdal in Children*

19. From at least 1999 through 2005, Defendant Janssen actively and aggressively promoted Risperdal for unapproved pediatric use and for unapproved medical conditions.

20. Upon information and belief, Defendant Johnson approved, ratified, and encouraged Defendant Janssen's actions described to follow.

21. In 1999, the FDA contacted Janssen regarding misleading advertising for the drug Risperdal. **Ex. C.**

22. For some or all of the period of time between 1999 and 2005, Janssen and Johnson knew that Risperdal posed certain health risks to children, including the risk of elevated levels of prolactin, a hormone that can stimulate breast development and milk production, which can result in gynecomastia in males.

23. The FDA approved label, from launch, indicated that Risperdal "elevates prolactin levels" but states that "the clinical significance of elevated serum prolactin levels is unknown for most patients."

24. Upon information and belief, one of Janssen and Johnson's Key Base Business Goals was to grow and protect share in the child / adolescent market. Janssen's 2001 Base Business Plan stated that the fastest growing market for Risperdal was pediatrics, with the use of Risperdal

“exploding” at a 17 percent rate of growth, for a total market share of \$340 million per year. Janssen recognized that Risperdal was used in children primarily for non-psychotic diagnoses: bipolar disorder (21%), autism (18%), ADHD (15%). Janssen also noted that Risperdal was typically prescribed in children “to control aggressive/impulsive behavior.”

25. Prior to the 2006 approval of use in children, the FDA repeatedly warned Janssen and Johnson against promoting Risperdal for use in children.

26. At times prior to 2006, and despite the FDA’s warnings, Janssen instructed its sales representatives to call on child psychologists as well as mental health facilities that primarily treated children for purposes of promoting sale of Risperdal.

27. Upon information and belief, Janssen instructed its sales representatives during this time to market Risperdal as safe and effective for symptoms of various childhood disorders –all non-FDA approved- such as attention deficit hyperactivity disorder, obsessive-compulsive disorder, oppositional defiant disorder, and autism.

28. Upon information and belief, two such mental health facilities that were contacted pursuant to this marketing campaign during the period of time discussed in this section of the Complaint were the Rivendell Psychiatric Center in Saint Johns, MI and the Saint Lawrence Medical Center in Lansing, Michigan.

29. Upon information and belief, Janssen also sponsored numerous advisory boards with child psychiatrists and speakers programs concerning “Risperdal in Children and Adolescents with Severe and Disruptive Behaviors and Below-Average IQ.”

30. Upon information and belief, Janssen prepared two plans for addressing the child and adolescent market in 2002: a business plan (“Risperdal Child and Adolescent Market Segment: 2002 Business Plan Summary”) and a tactical plan (“2002 Tactical Plan RISPERDAL Child and

Adolescent Segment: Reach New Heights with Risperdal in 2002”). Janssen identified four key business strategies:

- a. Understand the level of awareness of RISPERDAL in the child and adolescent market segment;
- b. Educate health care providers on therapeutic options for treating mental illness in children;
- c. Develop a child and adolescent public relations and media management plan; and
- d. Clarify FDA requirements and accelerate JRF program to obtain child and adolescent labeling.

31. In or about April of 2003, the FDA approved “M-Tabs,” a fast dissolving version of the Risperdal drug. Upon information and belief, Janssen’s records will reveal that its district managers encouraged contests and other incentives to promote this quick-dissolving Risperdal formulation in children.

32. Upon information and belief, in the San Antonio District, district managers encouraged “Risperdal ‘Back to School Bashing’” and proposed ice cream parties, snacks, and lunches as an effective way to deliver the message of M-Tabs use in the pediatric population.

33. Upon information and belief, notes from the District Manager’s Conference call on August 11, 2003 state that “[t]here is a very large market for M-TABS\* for children/adolescents!”

34. In an August 20, 2003 Field Conference Report, a full three years before FDA approval of Risperdal in minors for *any* purpose, one of Janssen’s District Managers praised a sales representative for an idea they had pertaining to promotion of M-Tabs to children, stating

[y]ou have a great idea for M-Tab starter kits by including lollipops or small toys to be included in the kit along with a coupon and a 1 box of sample. These will

be great to use on any child & adolescent psychiatrists that you have...Plan to have these made for our next work session. **Ex. D.**

35. During the times described herein, Janssen maintained “Call Notes” between its sales representatives and “Field Conference Reports” from their managers pertaining to their marketing contacts with doctors, psychiatrists, and facilities. Upon information and belief, once these reports are produced during discovery, they will reveal a pattern of Janssen sales representatives promoting Risperdal as safe and effective in controlling behavioral disturbances in children and adolescents. For example, it is believed that the notes will reveal the following:

- a. In or about 1997 and 1998, a Maryland Call Note indicated that the representative should “remind her [doctor] that risperdal is very effective and safe because she sees lots of children and adolescence [sic].”
- b. In or about 1997 and 1998, a Michigan Call Note indicated that the representative “sold him on efficacy and safety in children.”
- c. A 2000 Field Conference Report for New York stated that “I observed that prolactin was a concern with several of your customers. [Y]ou have a good understanding of prolactin and how to handle this objection with your customers. For example, Dr. H[] stated she sees prolactin related side effects quite often with Risperdal...You did a nice job of discussing how rare prolactin related side effects occur, how to manage it i.e. lowering the dose, and brought the discussion back to side effects that are not easily manager, i.e. diabetes.”
- d. A 2001 Call Note from Texas indicated that the representative “Discussed...proper dosing in children. Warned him about competition putting side effects out of context [sic] regarding R[isperdal] in children. Asked for starts/switches in aggression.”
- e. A 2001 Call Note from Virginia indicated that “INSERVICE FOR THE GROUP, WENT OVER RISPERDAL USE IN ADULTS AND CHILDREN, THE SYMPTOMS IT COVERS...”
- f. A 2002 Call Note from Washington indicated that “Dr. has not received information on conduct disorder and recent published articles. We reviewed efficacy of risperdone on aggression and hostility in special populations and doses.”
- g. A 2002 Call Note from New York indicatd that the physician the representative spoke to “[D]oesn’t see adhd but will rx [prescribe] when sees.”

- h. A 2002 Field Conference Report from Minnesota reveals that a manager praised a sales representative for downplaying the prolactin side effects risk to a doctor, stating that “[The doctor] then told you a story about a young woman who developed some prolactin side effects on Risperdal. Based on his comments it was clear prolactin was an issue of his. You handled his objection and issue perfectly by explaining that any drug that blocks D2 [dopamine] can have an effect on prolactin however the incidence of seeing side effects is very low. You then went onto explain that he may be able to decrease the dose and maintain the great efficacy that he is seeing with Risperdal and at the same time hopefully the side effect will subside. He agreed that this was a good idea and would give it a try.”
- i. In 2003, a Call Note from North Carolina revealed that the physician “Sees 30% kids, 40% adolescents, 30% adults...With kids-discussed serotonin profile page-lower does equate to efficacy in treatment of agitation, aggression-symptoms with behavioral problems.”
- j. A 2003 Call Note from Indiana revealed that the representative’s “[n]ext call remind him of the type of syms [symptoms] he can treat with Ris[perdal]. [P]aint the picture of a younger patient suffering from these sym [symptoms] and what ris[perdal] can do for them.”
- k. A 2004 Call Note from South Carolina revealed that the representative had a “brief follow up on use of Risperdal and moa [mechanism of action] that will treat anxiety and depressive symptoms. [E]mphasized the importance of dosing and how if dosed appropriately will treat odd [Oppositional Defiant Disorder] symptoms that present with adhd.”
- l. In a 2004 Call Note from Maryland, the representative stated the following: “Goal: agitated [sic]/aggression in children. Response: must rule out ADHD in children before rx [prescribing] atypical-Risperdal effectively treat[s] resistant depression at lower doses.”

*Jerad Short: One of the Many, Many Victims of Janssen and Johnson’s Risperdal Campaign*

36. Plaintiff Jerad Short was born in November of 1985.

37. In or about 1994, when Plaintiff Jerad Short was approximately 9-10 years old, he was diagnosed with bipolar disorder.

38. For a period of approximately four years, between 1994 and 1999, he received treatment for his bipolar disorder from physicians in the Lansing, Michigan area including Dr. Michael Vanderwalle, Dr. Michael Hickey, and Dr. Sarabjit Singh Tokhie.

39. Upon information and belief, at points in time prior to 1999, Defendants Janssen and/or Johnson directed information and marketing materials for Risperdal to one or more of the physicians listed in the previous paragraph.

40. Upon information and belief, at points in time prior to 1999, Defendants Janssen and/or Johnson directed other correspondence or communications to one or more of the physicians identified in the previous paragraph that were designed or intended to cause them to prescribe the drug to their adolescent patients who suffered from bipolar disorder.

41. At various times between 1994 and 1999, Plaintiff Short received treatment for his bipolar disorder at the St. Lawrence Hospital in Lansing, Michigan and at the Rivendell Psychiatric Center in St. Johns, Michigan.

42. Rivendell Psychiatric Hospital is mental health facility that provides services to pediatric and adolescent individuals. St. Lawrence also treats adolescents for mental health issues.

43. Upon information and belief, Defendants Janssen and/or Johnson directed information and marketing materials pertaining to Risperdal to one or more of the hospitals listed in the previous paragraphs, prior to 1999.

44. Upon information and belief, prior to 1999, Defendants Janssen and/or Johnson directed other correspondence or communications to one or more of the hospitals identified in the previous paragraph that were designed or intended to cause them to prescribe the drug to their patients.

45. At some or all of the times between 1994 and 1999, Mr. Short was prescribed Risperdal for his bipolar disorder. **Ex. J.**

46. At some or all of the times between 1994 and 1999, Mr. Short ingested the drug Risperdal for prolonged periods of time, in conformance with his physicians' direction.

47. Upon information and belief, Defendant Janssen and Johnson's unlawful marketing of Risperdal for unapproved, off label uses was, at least in part, the cause of Short's physicians' decision to prescribe and administer the drug to him for treatment of his conditions during this period of time.

48. Mr. Short has recently been diagnosed with gynecomastia. **Ex. K.**

49. Mr. Short's gynecomastia is the result of his ingestion of the drug Risperdal during his adolescence.

50. Mr. Short now will require surgery to correct the gynecomastia. *Id.* Mr. Short, therefore, will incur medical expenses to correct the physical manifestations of his gynecomastia.

51. Mr. Short has suffered, and continues to suffer, severe emotional distress, humiliation, embarrassment, mortification, fear, and outrage as a result of the physical deformity from which he suffers, resulting from the Defendants' wrongful actions.

52. Mr. Short, or persons acting on his behalf, have paid money for Risperdal proscriptions based on the false statements and assertions of the Defendants.

*Qui Tam Suits and Criminal Actions: Janssen and Johnson Publicly Admit to Unlawful Marketing of Risperdal in October of 2013.*

53. Plaintiff repeats and re-alleges the factual statements and legal assertions contained in the previous numbered paragraphs as if fully restated herein.

54. In or about February of 2010 Victoria Starr, Lynn Powell, Camille McGowan, Judy Doetterl, and Kurtis J. Barry, former employees of Defendant Janssen, came forward with allegations of Janssen's wrongful off-label promotion of Risperdal. These individuals filed a series of *Qui Tam* actions pursuant to the False Claims Act, 31 USC § 3729, and pursuant to a host of state law analogs to the Act.<sup>1</sup> The matters proceeded in the Eastern District of Pennsylvania, case numbers 4-cv-1529, 4-cv-5184, 5-cv-5436, and 10-cv-0098. **Ex. E.** Pursuant to the provisions of the False Claims Act, these Complaints were filed under seal and, therefore, were not available for public inspection when they were filed.

55. The United States intervened in the *Qui Tam* actions, pursuant to the terms and procedures of the False Claims Act. The United States also initiated a criminal prosecution against Janssen Pharmaceuticals, Inc. in the Eastern District of Pennsylvania for violation of 21 USC § 331(a), 333(a)(1) for "introduction of a misbranded drug into interstate commerce." This matter proceeded as Eastern District of Pennsylvania Case Number 13-605.

56. On October 29, 2013 the United States and Janssen Pharmaceuticals, Inc. entered into a plea agreement to resolve the criminal charges relating to the misbranding and off-label promotion of Risperdal. **Ex. G.** Janssen stipulated that "Between March 3, 2002 and December 31, 2003, "Janssen Pharmaceutica, Inc." [a predecessor to Defendant Janssen] caused shipments of Risperdal to be introduced into interstate commerce, and these shipments constituted misbranded drugs due to the conduct[.]" *Id.* Janssen agreed to pay the combined sum of \$400,000,000 to resolve the criminal portion of the claims against them, stemming from the misbranding of Risperdal. *Id.*

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<sup>1</sup> The theory here being that Janssen had caused payments to be made from Medicare and Medicaid, resulting from a pattern of fraudulent statements about the safety and efficacy of Risperdal, including the unlawful marketing of the drug to the adolescent market described previously.

57. On October 30, 2013 the Court ordered that the United States' Complaint in Intervention be unsealed. *Id.* The Complaint in Intervention contained specific information pertaining to the DOJ's investigation into Janssen and Johnson's actions, and the promotion of Risperdal. **Ex. F.** Prior to the unsealing of this document, Plaintiff did not know, and could not have known, of Janssen's aggressive marketing and promotion of off label use of the drug Risperdal.

58. On October 31, 2013 Defendants Janssen & Johnson entered into a Settlement Agreement resolving the Eastern District of Pennsylvania civil actions. **Ex. H.** In this agreement, Johnson and Janssen admitted, inter alia, that they "knowingly ... promoted the sale and use of Risperdal for conditions and for patients for which it was not approved as safe and effective by the Food and Drug Administration" and "made false and misleading statements about the safety and efficacy of Risperdal[.]" *Id.*

59. On November 4, 2013 the United States Department of Justice issued a press release and announced the results of the Risperdal litigation. The Press Release provided, in pertinent part, that

[i]n addition to promoting Risperdal for elderly dementia patients, from 1999 through 2005, Janssen allegedly promoted the antipsychotic drug for use in children and individuals with mental disabilities. The complaint alleges that J&J and Janssen knew that Risperdal posed certain health risks to children, including the risk of elevated levels of prolactin, a hormone that can stimulate breast development and milk production. Nonetheless, one of Janssen's Key Base Business Goals was to grow and protect the drug's market share with child / adolescent patients. Janssen instructed its sales representatives to call on child psychiatrists, as well as mental health facilities that primarily treated children, and to market Risperdal as safe and effective for symptoms of various childhood disorders, such as attention deficit hyperactivity disorder, oppositional defiant disorder, obsessive-compulsive disorder and autism. Until late 2006, Risperdal was not approved for use in children for any purpose, and the FDA repeatedly warned the company against promoting it for use in children. **Ex. I.**

60. Defendants knowingly and intentionally concealed their pattern of misrepresentations pertaining to the safety and efficacy of the drug Risperdal.

61. Defendants knowingly and intentionally obfuscated the fact that they engaged in activity to encourage medical professionals to prescribe the drug to children and adolescents –a group for whom the FDA had not approved the drug- for conditions not approved by the FDA for treatment.

62. Prior to Defendants’ late-October 2013 admission to this pattern of conduct, the Court’s late-October order unsealing the Civil Complaint, and the Department of Justice’s early-November press release, Plaintiff Short did not know, and through reasonable diligence could not have known, of Defendants’ knowing misrepresentations pertaining to the drug Risperdal that resulted in his development of gynecomastia.

**COUNT ONE: RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT,  
18 USC § 1962(C)**

*As against all Defendants*

63. Plaintiff repeats and re-alleges the factual matter and legal assertions contained in the previous numbered paragraphs as if fully restated herein.

64. 18 USC § 1962(c) provides that “[i]t shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity or collection of unlawful debt.”

65. At all relevant times, the following nonexclusive list of individuals and business entities constituted an “enterprise,” within the meaning of 18 USC §§ 1961(4) and 1962(c), in that they were “a group of individuals associated in fact”:

a. Defendant Janssen Pharmaceuticals, Inc. (f/k/a Janssen Pharmaceutica, Inc.), is individually a “person” within the meaning of 18 USC §§ 1961(3) and 1962(c), who associated with and/or participated in the conduct of said enterprise’s affairs,

b. Defendant Johnson & Johnson, Inc., is individually a “person” within the meaning of 18 USC §§ 1961(3) and 1962(c), who associated with and/or participated in the conduct of said enterprise’s affairs,

c. Individual sales representatives, the identities of whom are within the exclusive possession and control of Defendants Janssen and/or Johnson, who knowingly misrepresented the safety and efficacy of the drug Risperdal to medical care providers and facilities,

d. Individual district managers, the identities of whom are within the exclusive possession and control of Defendants Janssen and/or Johnson, who knowingly encouraged the sale representatives to misrepresent the safety and efficacy of the drug Risperdal to medical care providers and hospitals,

e. Such other managerial or executive level employees of the named Defendants, whose identities are in the sole possession and control of Defendants Janssen and/or Johnson, who proscribed, encouraged, facilitated, and otherwise aided the pattern of illicit conduct described herein.

65. The Defendants’ pattern of racketeering activity consisted of:

a. A scheme to defraud medical care providers, medical facilities and, ultimately, patients in order to obtain money or property by means of false or fraudulent pretenses and representations by knowingly, willfully, and repeatedly misrepresenting the safety and efficacy of the drug Risperdal.

- b. The sales representatives and district managers repeatedly and willfully representing that Risperdal was appropriate to treat certain conditions for which it was not approved, to treat individuals in age groups for which the drug was not approved, and by intentionally downplaying the seriousness of known side effects to the use of the drug and dangers in the use of the drug,
  - c. The sales representatives and district managers placing or causing to be placed in a post office or authorized depository for mail, matter that furthered the scheme to defraud, in violation of 18 U.S.C. § 1341,
  - d. The sales representatives and district managers transmitting, or causing to be transmitted, by means of wire, telephonic, or internet communication in interstate and foreign commerce matter that furthered the scheme to defraud (including, but not limited to, the telephonic communications mentioned herein), in violation of 18 USC § 1343,
  - e. Defendant Janssen and Johnson's executives, managers, and employees approving, ratifying, encouraging, and incentivizing the aforesaid conduct,
  - f. Defendant Janssen approving, ratifying, encouraging, and incentivizing the aforesaid conduct,
  - g. Defendant Johnson approving, ratifying, and encouraging the aforesaid conduct.
66. At all relevant times, the enterprise described above was engaged in, and its activities affected, interstate commerce and foreign commerce.
67. All of the predicate acts described above were related so as to establish a pattern of racketeering activity, within the meaning of 18 U.S.C. § 1962(c), in that their common purpose was to defraud patients such as Plaintiff Short, or persons or insurers paying medical claims on

his behalf, of property or money by causing them to pay monies for the drug Risperdal based on false statements as to the safety and efficacy of the drug; their common result was to defraud plaintiffs or others similarly situated of property or money; the defendants, acting individually or through their agents, directly or indirectly, participated in all of the acts and employed the same or similar methods of commission; plaintiffs or other similar persons were the victims of the fraudulent acts; plaintiffs or others similarly situated were the victims of the fraudulent acts; and/or the acts were otherwise interrelated by distinguishing characteristics and were not isolated events.

68. All of the predicate acts described above were continuous so as to form a pattern of racketeering activity in that the pattern of racketeering activity described herein occurred continuously for a period of not less than two years.

69. As a direct result of, and by reason of, the activities of the defendants, and their conduct in violation of 18 U.S.C. §§ 1962(c), Plaintiff has been injured in his business or property, within the meaning of 18 USC § 1964(c).

70. In particular, Plaintiff has suffered damages to his property because he will incur medical expenses as a direct and proximate result of Defendants' fraudulent acts.

71. Plaintiff, further, has suffered emotional distress including anxiety, depression, humiliation, mortification, fear, anger, and disgust as a result of Defendants' wrongful acts.

72. Plaintiff is, therefore, entitled to recover threefold the damages that he has sustained together with the cost of the suit, including reasonable attorneys' and experts' fees.

73. Due to Defendants' fraudulent concealment of their wrongful actions, as delineated herein, Plaintiff could not have discovered the fact of his injury prior to October of 2013 when Defendants admitted publicly to same. This action, therefore, is timely filed.

**COUNT TWO: RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT,  
18 USC § 1962(d)**

*As against all Defendants*

74. Plaintiff restates and re-alleges the factual statements and legal assertions contained in the previous numbered paragraphs as though fully restated herein.

75. The aforesaid Defendants, together with the presently unidentified sales representatives, district managers, managers, and executives, conspired together and with other parties to conduct or participate, directly or indirectly, in the conduct of the affairs of the enterprise through a pattern of racketeering activity (as described above) in violation of 18 USC § 1962(d).

76. As stated previously, as a direct and proximate result, and by reason of the activities of the defendants, and their conduct in violation of 18 USC § 1962(d), Plaintiff has been injured in his business or property, within the meaning of 18 USC § 1964(c).

77. Plaintiff is, therefore, entitled to recover threefold the damages that he has sustained together with the cost of the suit, including reasonable attorneys' fees and experts' fees.

78. Due to Defendants' willful concealment of their wrongful and fraudulent actions, as delineated herein, Plaintiff could not have discovered the fact of his injury prior to October of 2013 when they admitted publicly to same. This action, therefore, is timely filed.

**COUNT THREE: VIOLATION OF MICHIGAN'S CONSUMER PROTECTION ACT,  
MCL § 445.901 *et seq***

*As against All Defendants*

79. Plaintiff restates and re-alleges the factual statements and legal assertions contained in the previous numbered paragraphs as though fully restated herein.

80. As described herein, the Defendants knowingly and intentionally, over the period of several years, misrepresented the safety and efficacy of the drug Risperdal in order to increase sales of

the drug. In so doing, they committed unfair, unconscionable, and deceptive methods, acts, and practices in the conduct of trade and commerce, in violation of MCL 445.903 *et seq.* In particular, but not way of limitation:

- a. Defendants knowingly marketed Risperdal to populations which the FDA had not approved its use, for conditions which the FDA had not approved, thus “[r]epresenting that goods ... have ... characteristics, ... uses [or] benefits ... that they do not have” in violation of MCL 445.903(c).
- b. Defendants’ implied in their promotion of Risperdal that it was FDA approved, and otherwise safe to treat such conditions and to be administered to such persons, thus “causing a probability of confusion or misunderstanding as to the ... approval, or certification ... of goods” in violation of MCL 445.903(a)
- c. Defendants downplayed the significant risks that went with Risperdal, most notably the high risk of developing gynecomastia as a result of the prolactin imbalance resulting from its use, thus “[f]ailing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer” in violation of MCL 445.903(s), “[m]aking a representation of fact or statement of fact or statement of fact material to the transaction such that a person reasonably believes the represented or suggested state of affairs to be other than it actually is” in violation of MCL 445.903(bb), and “[f]ailing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner” in violation of MCL 445.903(cc).

81. As a result of Defendants' willful misconduct, Plaintiff will suffer medical expenses in treating his gynecomastia. In addition, he has suffered emotional distress as a result of the condition he developed.

82. Plaintiff may recover his actual damages and reasonable attorney's fees pursuant to MCL 445.911(2).

83. Due to Defendants' willful concealment of their wrongful and fraudulent actions, as delineated herein, Plaintiff could not have discovered the fact of his injury prior to October of 2013 when they admitted publicly to same. This action, therefore, is timely filed.

#### **COUNT FOUR: PRODUCTS LIABILITY**

*As against All Defendants*

84. Plaintiff restates and re-alleges the factual statements and legal assertions contained in the previous numbered paragraphs as though fully restated herein.

85. Defendants manufactured, produced, marketed, and sold the drug Risperdal to Michigan residents.

86. Use of Risperdal carried a high risk of increased prolactin production, which could result in development of the physical deformation gynecomastia.

87. The risk of prolactin imbalance, and development of gynecomastia, was known to Defendants Johnson and Janssen at some or all of the times that they marketed the drug to Michigan residents.

88. Defendants had a duty to warn users of Risperdal of the known risk of prolactin imbalance, and risk of developing gynecomastia, from use of the drug.

89. Risperdal's label listed prolactin problems, but failed to particularly list development of gynecomastia as a known side effect.

90. Further, Defendants knowingly downplayed the risk of developing gynecomastia in their advertising and marketing efforts.

91. Defendant Johnson was aware of, approved, and ratified Defendant Janssen's decision to fail to highlight the risk of development of gynecomastia in its advertising and marketing materials, and of its decision to downplay the known risk of developing gynecomastia in its marketing to physicians and mental health facilities.

92. Jerad Short was prescribed Risperdal by his physicians when he was between the ages of 10 and 14.

93. Defendants' failure to warn of the risks of developing gynecomastia that came with use of the product was the actual and proximate cause of Plaintiff's physicians' decision to prescribe the drug.

94. Defendants' decision to downplay the known risks of developing gynecomastia in its marketing to physicians and mental health facilities was the actual and proximate cause of Plaintiff's physicians' decision to prescribe him the drug.

95. Defendants' actions described herein are the actual and proximate cause of Plaintiff's development of gynecomastia.

96. Defendants knowingly and intentionally concealed their wrongful actions. Plaintiff did not know, and could not have known, about this conduct until Defendants' October 2013 guilty plea. Plaintiff's claim was filed within the statutory limitations period from that date.

97. Plaintiff has suffered significant emotional pain and distress as a result of developing this physical deformity attributable to the Defendants' wrongful conduct.

98. Plaintiff will suffer medical expenses resolving the physical deformity that he has developed, as a result of ingesting Defendants' product.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff Jerad Short requests that this Honorable Court grant them the following relief against Defendants Janssen and Johnson:

1. His past and prospective medical expenses so wrongfully incurred in resolving the gynecomastia that he has developed as a result of Defendants' wrongful acts described herein,
2. Compensation for his humiliation, embarrassment, outrage, frustration, sadness, and other emotional distress he has suffered resulting from the physical condition,
3. Exemplary and punitive damages, as may be appropriate given Defendants' willful, wanton, and malicious conduct,
4. Attorney's Fees, in an amount to be determined at the conclusion of this action,
5. Pre and Post judgment interest, and
6. Such other relief as this Court may deem just and equitable.

Respectfully Submitted,

Date: September 30, 2014

/s/ Collin H. Nyeholt  
Collin H. Nyeholt (P74132)  
Attorney for the Plaintiff